

QA: QA

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE**

AUDIT REPORT USGS-ARC-01-11

OF THE

U.S. GEOLOGICAL SURVEY

**SUPPORT OF THE
YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT**

AT

DENVER, COLORADO

JUNE 25-29, 2001

Prepared by:_____

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Date:_____

Approved by:_____

**Robert W. Clark
Director
Office of Quality Assurance**

Date:_____

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit USGS-ARC-01-11, the audit team determined that, with the exception of the identified conditions adverse to quality (CAQ), the U.S. Geological Survey (USGS) at Denver, Colorado, is satisfactorily and effectively implementing the examined portions of the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description* (QARD) and applicable implementing procedures.

QA Program Sections 1.0, 2.0, 4.0, 5.0, 6.0, 7.0, 12.0, 15.0, 16.0, 17.0, Supplements I, II, III, V, and Appendix C were determined to be effectively implemented based on the activities evaluated during the audit. Currently, Sections 3.0, 8.0, 9.0, 10.0, 11.0, 13.0, 14.0, 18.0, Supplement IV, and Appendices A and B are not being implemented by the USGS.

The audit team identified three CAQs. The first CAQ is addressed in Deficiency Report (DR) USGS-01-D-105. This DR identified that USGS had inadequate measuring and test equipment (M&TE) calibration documentation.

The two remaining CAQs requiring only remedial actions were identified and corrected during the audit (CDA).

CDA #1 addressed an inappropriate method used in one Scientific Notebook (SN) to record daily entries.

CDA #2 addressed the lack of required compliance and technical reviews of SNs when approaching one year.

The audit team evaluated the effectiveness of corrective actions for six previously issued USGS deficiencies. The audit team identified a potential emerging trend issue in the QA program implementation area of M&TE control. This potential trend issue was discussed with the Navarro Quality Services (NQS) Trend Coordinator and the issue is being investigated for input into the current trend report. The effectiveness evaluation results are documented in Section 5.5.3 of this report.

In addition there was one recommendation resulting from the audit as documented in Section 6.0 of this report for the USGS management consideration.

2.0 SCOPE

Auditors representing the DOE Office of Quality Assurance (OQA) conducted a compliance-based audit to evaluate the USGS implementation of the OCRWM QA Program as described in the QARD and implementing procedures. The audit team,

through interviews of cognizant personnel, reviews of documentation, and evaluation of procedures, assessed the adequacy and effectiveness of the USGS implementation of the QA program. The audit was conducted at the USGS offices in the Denver Federal Center, Denver, Colorado.

The audit team reviewed the status of six closed OCRWM deficiency documents that had been generated during the previous year of OQA audits and surveillances to determine the effectiveness of completed corrective actions by the USGS.

In accordance with the approved audit plan, the following QA program sections were evaluated:

QA PROGRAM SECTIONS

1.0	Organization
2.0	QA Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	QA Records
Supplement I	Software (limited to software not related to Analysis and Model Report {AMR}/Process Model Report {PMR} development)
Supplement II	Sample Control
Supplement III	Scientific Investigation (limited to review of entries in SNs since last audit)
Supplement V	Control of the Electronic Management of Data (limited to the USGS activities not related to AMR/PMR processes)
Appendix C	Monitored Geologic Repository

The following QA program sections were not evaluated, since the USGS is not currently implementing them:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage and Shipping
14.0	Inspection, Test and Operating Status
18.0	Audits

Supplement IV Field Surveying
Appendix A High-Level Waste Form Production
Appendix B Storage and Transportation

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

<u>Name/Title/Organization/Company</u>	<u>QA Program Section</u>
James V. Voigt, Audit Team Leader, NQS	1.0, 2.0, 16.0 and Supplement V
James Blaylock, Auditor, DOE/OQA	4.0, 7.0, and 12.0
James Flaherty, Auditor, NQS	15.0 & Supplements II and III
Pat Auer, Auditor, NQS	5.0, 6.0, 17.0 and Supplement I

4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED

A pre-audit meeting was held at the USGS offices on June 25, 2001. Daily debriefings were conducted to apprise the USGS management and staff of the progress of the audit and any conditions adverse to quality. A post-audit meeting summarizing the audit was held at the USGS offices on June 29, 2001. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment 1, "Personnel Contacted During the Audit."

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, with the exception of one CAQ, DR USGS-01-D-105 the USGS is satisfactorily and effectively implementing the examined portions of the QARD and applicable implementing procedures. The results for each QA program section evaluated are contained in Attachment 2, "Summary Table of Audit Results."

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders or immediate corrective actions initiated as a result of this audit.

5.3 Audit Activities

Attachment 2, "Summary Table of Audit Results," provides results for each QA program section audited. The details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

5.4 Technical Audit Activities

An audit of technical activities was not included in the scope of this audit.

5.5 Summary of Conditions Adverse to Quality

One DR, USGS-01-D-105, with conditions adverse to quality was issued as a result of this audit. Details of this DR are documented in Section 5.5.2 of this report.

Two deficient conditions identified required only remedial actions and were CDA. The CDA conditions are described in detail in Section 5.5.3 of this report.

5.5.1 Corrective Action Requests

There were no CARs issued as a result of this audit.

5.5.2 Deficiency Reports (DR)

USGS-01-D-105

M&TE were checked at the USGS in Denver, Colorado. M&TE included multimeters, vacuum gauges, a mass spectrometer, and balances. In one laboratory, a Satorius balance had a current calibration sticker, however, the backup calibration documentation indicated that on two occasions the balance was out of tolerance for the “as found” condition. Despite the out-of-tolerance condition, no Out of Calibration Report or Nonconformance Report had been initiated.

Scientific Notebook SN-0099, V1, pages 68-84, was used to document the calibration of heat dissipation probes (HDP). The results for this calibration are recorded, however, the method used is not adequately referenced, nor are all required calibration information included. Furthermore, upon checking the master M&TE list it was found that the HDPs were not represented on the master list.

The M&TE database list was used to sort active M&TE overdue for calibration. The overdue equipment listed was lengthy and appeared excessive. The audit team noted that a majority of the calibrated equipment was assigned to a single Principle Investigator, who has no current work on the Yucca Mountain Project.

5.5.3 Deficiencies Corrected During the Audit (CDA)

Deficiencies considered isolated in nature and requiring only remedial action can be CDA. Two deficiencies meeting these criteria were CDA and are identified below:

CDA #1 addressed one Scientific Notebook, SN-USGS-SCI-126-V1, wherein entries were composed on a laptop computer on a daily basis however the entries were not placed in the SN on a daily basis but instead at the end of the week. Data entries for several dates were printed up on a single sheet of paper and then attached to the SN page. The attachment was appropriately pasted into the SN and initialed and dated with the date of the last days work entry. The SN author believed this to be an acceptable method to record daily SN entries. The preferred method of recording SN entries was discussed with management and the SN author. This appeared to be an isolated case with no impact to SN or data inputs. In addition the SN author is now correctly making SN entries. The audit team noted that other than the detail discussed above this SN was very well maintained.

CDA #2 addressed the lack of compliance and technical reviews of SNs when approaching one year (52 weeks) without a previous review being performed. The SN status log indicated five SNs were at week 54 without the reviews being initiated. The reviews were initiated during the audit and there was no adverse impact to data. This condition is considered closed.

5.5.4 Follow-up of Previously Issued Deficiency Documents

Six OCRWM deficiency documents that had been generated during the previous year were examined to determine the effectiveness of completed corrective actions by the USGS. One concern was identified during the follow-up of previously documented deficiencies. Two DRs identified below (USGS-00-D-123 and USGS-01-D-005) concern similar deficient conditions of inadequate control of M&TE lists, these are similar to the deficiency identified and documented on DR USGS-01-D-105. This potential emerging trend issue was discussed with the NQS Trend Coordinator and will be investigated for the upcoming trend report.

DR USGS-01-D-004

This DR noted the USGS failure to adequately document a calibration procedure deviation regarding recording sample weight data at a less accurate level than the specified accuracy (0.1 lbm versus 0.01 lbm). No additional occurrences of this deficient condition were identified during the audit.

DR USGS-01-D-005

This DR is still open and is scheduled to close on 7/30/01. This DR concerns inadequate M&TE calibration documentation, it also concerns M&TE in use that was not on the M&TE list. An occurrence of this deficient condition was identified during the current audit. Also, see DR USGS-00-D-123 below.

DR USGS-00-D-030

This DR addresses the USGS failure to use procedures rather than SNs for performing requested testing. No additional occurrences of this deficient condition were identified during the audit.

DR USGS-00-D-122

This DR addresses the USGS failure to perform planning by not completing a Development Plan prior to the creation of a technical product. No additional occurrences of this deficient condition were identified during the audit.

DR USGS-00-D-123

This DR addresses M&TE used to determine material thermal properties that was not calibrated by an OCRWM qualified supplier. In addition this DR addresses the USGS failure to maintain an up-to-date M&TE list. One occurrence of this deficient condition was identified during the audit. Also, see DR USGS-01-D-005 above.

DR USGS-00-D-124

This DR addresses record packages transmitted by the USGS and accepted by the Yucca Mountain Site Characterization Project (YMP) Records Processing Center, with obliterations and other corrections. No additional occurrences of this deficient condition were identified during the audit.

6.0 RECOMMENDATION

One recommendation resulting from the audit is presented below for the USGS management's consideration:

The USGS should establish a more rigorous approach to ensuring that SNs receive the requisite minimum annual review that would enhance the USGS SN process.

7.0 LIST OF ATTACHMENTS

Attachment 1: "Personnel Contacted During the Audit"

Attachment 2: "Summary Table of Audit Results"

Attachment 1
Personnel Contacted During the Audit

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Anderson, Alexandra	USGS/Administrative Secretary		X	
Chaney, Thomas H.	USGS/Chief, Regulatory and Quality Support Team	X	X	X
Chornack, Michael P	USGS/Team Chief, Scientific Synthesis Team	X	X	X
Craig, Robert W.	USGS/Technical Project Officer	X	X	X
Earle, John	USGS/Hydrologist		X	
Golos, Joyce L.	USGS/Administrative Officer	X	X	X
Hall, Valerie	USGS- Pacific Western Technologies (PWT)/ QA Implementation Specialist (QAIS)	X		X
Hersh, Barbara	USGS- PWT/Procurement Specialist	X	X	X
Hommel, Robert	USGS-PWT/Hydrologic Technician		X	
Hudson, David	USGS/Hydrologist		X	
Jhoon-Yen, Anne	USGS/Records Management Specialist	X	X	X
Kurzmack, Mark	USGS-PWT/Senior Scientist		X	X
Losasso, Jacqueline	USGS/Instructional Systems Specialist	X	X	X
Marshall, Brian D.	USGS/Hydrologist	X		X
McKinley, Patrick W.	USGS/Data Coordinator	X		
Miller-Corbett, Cynthia	USGS/Hydrologist		X	
Moscatti, Richard	USGS/Geologist		X	
Motyl, Pamela	USGS-PWT/QA Specialist	X	X	X
Mustard, Martha H.	USGS/Hydrologist	X	X	X
Oliver, Thomas	USGS-PWT/Hydrologist		X	
Parks, Bruce	USGS/Team Chief, Operational Support Team	X		X
Scofield, Kevin	USGS-PWT/Geologist		X	
Sheaffer, Patricia	USGS-PWT/Supervisor QAIS		X	X
Sinks, Donna J.	BSC On-Site QA Representative	X	X	X
Striffler, Peter	USGS/Hydrologist		X	
Tucci, Patrick	USGS/Hydrologist		X	
Washington, Toni	USGS-PWT/QAIS			X
Whiteside, Ardell	BSC On-Site QA Representative	X	X	X

Attachment 2

Summary Table of Audit Results

QA Section/ Activities	Document Review	Check-list Pages	Deficiencies	Rec	Program Adequacy	Procedure Compliance	Over all
1.0	YMP-USGS-QMP-1.01, R7, M1 &DOE/RW-0333P, R 10	1-5			SAT	SAT	SAT
2.0	AP-2.1Q, R 1, ICN 0, BSCN 1 AP-2.2Q, R 0, ICN 0 AP-2.14Q, R 0, ICN 1 AP-2.17Q, R 0, ICN 0,BSCN1 AP-2.19Q, R 0, ICN 0 AP-2.21Q, R1, ICN 0	6-7 8-9 10-12 13-15 16 17-21			SAT SAT SAT SAT SAT SAT	SAT SAT SAT SAT SAT SAT	SAT
4.0	YMP-USGS-QMP 4.01. R 10 YMP-USGS-QMP 4.02, R 8, M 1	22-24 25-27			SAT SAT	SAT SAT	SAT
5.0	DOE/RW-0333P, R 10 YMP-USGS-QMP 3.07, R 6 YMP-USGS-QMP 5.01, R 8, M 1 & M 2 YMP-USGS-QMP 5.03, R 10, M 1	28-30 31-33 34-35			SAT SAT SAT SAT	SAT SAT SAT SAT	SAT
6.0	AP-6.1Q, R 6 AP-6.28Q, R 0, BSCN 1 YMP-USGS-QMP-6.01, R 7	36-38 39-40 41-42			SAT SAT SAT	SAT SAT SAT	SAT
7.0	AP-7.4Q, R 4, ICN 0	43-45			SAT	SAT	SAT
12.0	AP-12.1Q, R0, ICN 1	46-52	USGS-01-D-105		SAT	UNSAT	SAT
15.0	AP-15.2Q, R 0, ICN 0	53-54			SAT	SAT	SAT
16.0	AP-16.1Q, R 4, ICN 1 AP-16.4Q, R 0, ICN 0	55-57 58			SAT SAT	SAT SAT	SAT
17.0	AP-17.1Q, R 1, ICN 2	59-61			SAT	SAT	SAT
Supplement I	AP-SI.1Q, R 2, ICN 4	62-69			SAT	SAT	SAT
Supplement II	YAP-SII.4Q, R 2, ICN 1 YMP-USGS-QMP 8.01, R 4, M 1	70-73 73-75			SAT SAT	SAT SAT	SAT
Supplement III	SP-SIII.1Q, R 1, ICN 0	76-80	CDA #1 CDA #2	1	SAT	SAT	SAT
Supplement V	AP-SV.1Q, R 0, ICN 1	81-85			SAT	SAT	SAT
Appendix C	Included in Sections 2.0, 4.0, 7.0, and 15.0	--			SAT	SAT	SAT
TOTALS		85 PAGES	1 DR 2 CDAs	1	SATISFACTORY		

Rec - Recommendation